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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,380	08/30/2001	S. Grant Mulholland	10303-2 US	7757

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DANIEL A. MONACO, ESQ.  
DRINKER BIDDLE & REATH, LLP  
ONE LOGAN SQUARE  
18TH AND CHERRY STREETS  
PHILADELPHIA, PA 19103-6996

EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/943,380	<b>Applicant(s)</b> MULHOLLAND ET AL.	
	<b>Examiner</b> Ann Y. Lam	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1-6, 8-64 and 73-75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-64 and 73-75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8-11, 13-15, 18-23, 32-36, 39-42, 44-50, 58, 61, and 64 are rejected under 35 U.S.C. 102(e) as being anticipated by D'Augustine et al., 6,416,779.

As to claims 1, 33, 61 and 64, D'Augustine et al. disclose a base member (47) that is non-meltable; a reinforcement (44) that is non-meltable and has a length having a first end and a second end, said first end attached to said base member and projecting from said base member; and a meltable portion (i.e., medication in 43) formed around a portion of said length of said reinforcement, said meltable portion having a diameter which tapers from said second end toward said first end, see Figure 6.

As to claims 2, 34, the base member (47) is shaped for handling.

As to claims 3, 4, 35, 36, the base member (47) is ellipsoid.

As to claim 39, the base member (47) is sized to fit within the labia minora.

As to claims 8, 13, 22, 40, 44 and 49, the suppository is comprised of polymers, see column 15, lines 18-22.

As to claims 9, 10, 41, the reinforcement first end is considered embedded within the base member, and projects perpendicular from said base member, see Figure 6.

As to claims 11, 42, the reinforcement (44) comprises a rod.

As to claim 14, the reinforcement is sized such that upon insertion into the urethra, the second end of the reinforcement is entirely within the meltable portion.

As to claim 15, the second end of the reinforcement (44) extends outside the meltable portion, see Figure 6.

As to claims 18-21, 45-48, the reinforcement (44) comprises a restraint.

As to claims 23, 50, the meltable portion comprises the therapeutic agents as claimed, see column 20, lines 39-43.

As to claim 32, 58, the meltable portion is capable of melting within about 2 minutes to about 60 minutes.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24, 25, 31, 51, 52, 57, 62, 63 and 73-75 are rejected under 35 U.S.C.

103(a) as being unpatentable over D'Augustine et al., 6,416,779.

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D'Augustine et al. disclose the invention substantially as claimed (see above).

However, with respect to claims 16, 17, 24, 25, 30, 31, 51, 52, 57, 59, 60 and 73-75, D'Augustine et al. do not disclose the dimensions as claimed. However, it would have been obvious to form the meltable portion having the dimensions as claimed, as would be necessary to fit inside the vagina of patients of various sizes, as taught by D'Augustine et al.

As to claims 62 and 63, it would have been obvious to wait for about 1 minute to about 10 hours to deliver the therapeutic agent, as may be necessary to deliver the agent.

#### ***Allowable Subject Matter***

Claims 5, 6, 12, 26-29, 37-38, 43, 53-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the combination of elements including a grooved base member, or a roughened base member, or a reinforcement being comprised of a lattice or mesh, was not found in the prior art search.

#### ***Response to Arguments***

Applicant's arguments filed December 29, 2003 have been fully considered but they are not persuasive. Applicant argues that none of the materials

disclosed by D'Augustine for the foam portion (43) is meltable, and that assuming that the medication was meltable, however, the foam portion (43) defining the tapered member for the tampon device will not melt (see page 2 of Applicant's response).

In response, Examiner asserts that the medication is considered the meltable portion formed around a portion of the length of the reinforcement (44) and having a diameter which tapers, as claimed by Applicant. Thus, it is irrelevant as the rejection, that the foam portion (43) will not melt.

Applicant also argues on page 2 that the reinforcement (44) is not embedded within the base member (47), but rather is adjacent to it. Examiner asserts that the reinforcement is embedded within the base member to the extent that the member (47) is attached to member (44) (see column 15, lines 20-22).

Applicant argues that Augustine does not disclose that an end of the reinforcement opposite the base member extends outside the meltable portion. Examiner asserts that the end opposite the base member includes a portion that remains outside the meltable portion (see Figure 6).

Applicant argues on page 3 that Augustine does not disclose that the reinforcement comprises one or more restraints along the portion of the length of the reinforcement, but rather the tube (44) is uniform along the length that is surrounded by the tapering foam portion (43).

In response, Examiner points out the tube (44) is not entirely uniform, but rather has an end that tapers to a wider width until it becomes cylindrical (see Figure 6.) The

cylindrical portion is considered a restraint, i.e., a protrusion having the form of a rod, as claimed by Applicant.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L.



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

03/22/04